(7-3)

OCT 1 9 2004

510(K) SUMMARY

HandSTC

510(k) Number K042492

Applicant's Name:

NiTi Medical Technologies Ltd.
1 Hatzoran st., P.O.Box 8634
Netanya 42506, Israel
Tel.: 972-9-865-0610
Fax: 972-9-835-0127

Contact Person:

Orly Maor
NiTi Medical Technologies Ltd.
1 Hatzoran St., P.O.Box 8634
Netanya 42506, Israel
Tel.: 972-9-865-0610/102
Fax: 972-9-835-0127
orly@nitimed.com

And/or

Jonathan S. Kahan, Esq.
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109
Tel: (202) 637-5794
Fax: (202) 637-5910

Date Prepared:

September 2004

Trade Name:

HandSTC.

K042202 (2-3)

Classification Name:

IMPLANTABLE STAPLE

Classification:

The FDA has classified implantable staple as class II device (product code GDW, Regulation No. 878.4750) and they are reviewed by the Division of General and Restorative Devices.

Predicate Devices:

- Proximate™ TVC55 Linear Cutter and Stapler (Ethicon Endo-Surgery, Inc. USA) cleared under K892927.
- Multifire GIA 60 stapler (United States Surgical Cooperation, UAS) cleared under K843603.
- Universal Endo GIA 60 (United States Surgical Cooperation, UAS) originally cleared under K892233 and K900129.

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Intended Use:

The NiTi HandSTC has applications throughout the alimentary tract in surgeries for resection, transaction, and the creation of anastomoses.

Device Description:

The NiTi HandSTC is a palm size linear cutter and stapler whose main parts are housed together enabling one hand operation by sequential pressing on the device lever.

The HandSTC applies 56 titanium staples in a line approximately 60mm long. The unformed staples are "U" shape which closed to form "B" shape. When the device is open the distance between the cartridge and the anvil is 4 cm.

The HandSTC device is supplied with one cartridge and can be reloaded for a total of 8 firings

The reloads are available in two sizes:
Blue- unformed staple leg height is 3.5 mm, staple dimension when closed is 1.5 mm. This cartridge closes to a gap of 0.8 mm and it is used for standard tissue and gastrointestinal applications.

Green- unformed staple leg height is 4.5 mm, staple dimension when closed is 2.0 mm. This cartridge closes to a gap of 1.3mm and it is used for gastrointestinal tract and thick tissues such as stomach and rectum applications.

Substantial Equivalence:

Based on validations and performance testing results, NiTi Medical Techologies Ltd. believes that the HandSTC is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2004

NiTi Medical Technologies Ltd
c/o Mr. Jonathan S. Kahan, Esq.
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, D.C. 20004

Re: K042492
Trade/Device Name: HandSTC
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: September 3, 2004
Received: September 17, 2004

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K042492 (1 of 1)

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: HandSTC

Indications for Use:

The NiTi HandSTC has applications throughout the alimentary tract in surgeries for resection, transaction, and the creation of anastomoses.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042492